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Assessment of Difference in Haemoglobin Percentage Improvement Between Lecithinum 12C and Lecithinum 12C with Ferrum Phosphoricum 6X Combination in Anaemic Individuals in Age group of 10–60 Years.

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Abstract

Anaemia remains a major public health concern in India, and it frequently produces fatigue, weakness and a reduced capacity for work. The present study compared changes in haemoglobin (Hb) and in fatigue, measured with the Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F) scale, among anaemic individuals aged 10 to 60 years who received either Lecithinum 12C alone or Lecithinum 12C combined with Ferrum phosphoricum 6X. A six-month randomized controlled trial was conducted at the outpatient department and associated camps of Motiwala Homoeopathic Medical College and Hospital, Nashik. Forty-eight participants were allocated by odd and even case numbering to a combination group (n = 24) or to a group receiving Lecithinum 12C with placebo (n = 24). Haemoglobin was assessed by complete blood count, fatigue was assessed with the FACIT-F scale, and within-group and between-group comparisons were made with paired and unpaired t-tests. Mean haemoglobin rose from 10.26 to 10.84 g/dl in the combination group and fell from 10.20 to 9.81 g/dl in the control group, giving a between-group difference in haemoglobin change of approximately 0.96 g/dl. The mean FACIT-F score improved by 5.38 points in the combination group and declined by 4.50 points in the control group. These findings suggest a greater improvement in the combination group; however, the small sample, the single-centre setting and the absence of a conventional-treatment comparator limit the conclusions that can be drawn. The combination should not be regarded as a substitute for established anaemia care.

Keywords: Anaemia; haemoglobin; Lecithinum 12C; Ferrum phosphoricum 6X; FACIT-F; homoeopathy; randomized controlled trial.

Introduction

Anaemia is a condition in which the haemoglobin concentration of the blood measures below the level expected for a person's age, sex and physiological status. It is one of the most common nutrition-related problems in the world and is especially frequent among pregnant women and young children (1). Iron deficiency is the commonest cause, and it arises from a poor intake of iron-rich food, reduced absorption, increased demand during growth, pregnancy and lactation, and blood loss from heavy menstruation or parasitic infection. Affected patients usually present with easy fatigability, breathlessness, pallor, swelling of the feet and menstrual disturbances, and adolescents may additionally show impaired growth.

The burden of anaemia in India is substantial. A systematic review and meta-analysis of Indian studies reported a high pooled prevalence across age and physiological groups. According to the National Family Health Survey-5 (2019–2021),

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anaemia affected 67.1% of children aged 6 to 59 months, 57.0% of women aged 15 to 49 years, 52.2% of pregnant women, 59.1% of adolescent girls, 31.1% of adolescent boys and 25.0% of men aged 15 to 49 years (11, 12).Despite the availability of conventional iron supplements, many patients show inadequate improvement or experience adverse effects. Homoeopathic medicines are believed to act at the dynamic level and to improve assimilation. Lecithinum has been used in homoeopathy for anaemia in the 12C potency, and Ferrum phosphoricum, a biochemic salt present in the haemoglobin of red blood cells, is among the most frequently indicated medicines (2, 3). Ferrum phosphoricum has shown benefit in improving haemoglobin in schoolchildren, adolescent girls and children with anaemia (4–8). Other studies have compared homoeopathic medicines with the similimum in anaemia (9), and one comparative study has examined Lecithinum 12C against individualized medicine given together with Ferrum phosphoricum 6X in females (10).However, high-quality randomized trials that directly compare Lecithinum alone with the combination of Lecithinum and Ferrum phosphoricum have been lacking.

The research question was whether there is a statistically significant difference in the improvement of haemoglobin, over six months, between anaemic individuals aged 10 to 60 years treated with Lecithinum 12C alone and those treated with Lecithinum 12C combined with Ferrum phosphoricum 6X. The alternative hypothesis held that a significant difference exists in the improvement of haemoglobin percentage between the two groups, while the null hypothesis held that no such difference exists.

The aim of the study was to evaluate and compare the effectiveness of the two regimens in improving haemoglobin in anaemic individuals aged 10 to 60 years. The primary objectives were to compare the mean change in haemoglobin, measured by complete blood count, and to compare the level of fatigue, measured by the FACIT-F scale score (13), between the two groups. The secondary objectives were to assess haemoglobin improvement across the age groups of 10 to 20, 21 to 30, 31 to 40, 41 to 50 and 51 to 60 years, to assess it according to sex, and to assess the changes in grades of anaemia before and after treatment.

Materials and methods

This was a randomized controlled trial of six months' duration conducted at the outpatient department of Motiwala Homoeopathic Medical College and Hospital, Nashik, and in camps organized by the institution. Written informed consent was obtained from all participants, and Forty-eight patients were enrolled and allocated to two groups of 24 each by odd and even numbering of cases. Odd numbers formed Group 1, the study group, and even numbers formed Group 2, the control group. Patients were eligible if they had been diagnosed with anaemia, were aged 10 to 60 years, had a haemoglobin of 8 to 12.9 g/dl as adult males or 8 to 11.9 g/dl as adult females or children, were willing to give written informed consent, and were willing to complete the six-month treatment and follow-up schedule. Patients were excluded if they had severe anaemia (haemoglobin below 7.0 g/dl) requiring blood transfusion or urgent conventional treatment, were younger than 10 or older than 60 years, had a known malignancy, renal failure or other severe systemic disease affecting haemoglobin, were pregnant or lactating, had received conventional anti-anaemic treatment such as iron tablets or injections within the previous four weeks, or had haemoglobinopathies or abnormal red blood cells.

Anaemia was defined as a haemoglobin below 13 g/dl in men and below 12 g/dl in women (1), and grades of anaemia were assigned according to the guidelines of the World Health Organization. Group 1 received Lecithinum 12C, four pills twice daily, together with Ferrum phosphoricum 6X, two tablets twice daily, for 15 days. Group 2 received the same dose of Lecithinum 12C together with Saccharum lactis 30 as a placebo, four pills twice daily, for 15 days. Treatment was repeated according to clinical need throughout the study, and follow-up was done every 15 days. Haemoglobin by complete blood count and the FACIT-F score were recorded at baseline and at the end of treatment.

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Pre-treatment and post-treatment haemoglobin and FACIT-F scores were compared within each group by the paired t-test and between the groups by the unpaired t-test with 46 degrees of freedom. The between-group difference in haemoglobin change was 0.96 g/dl with a standard error of the difference of 0.0717, and the calculated t-value was 2.671, which was greater than the critical value at the 5% level of significance. A patient was considered improved when the post-treatment haemoglobin was higher than the baseline value. The study report interpreted this result as statistically significant and rejected the null hypothesis.

Results

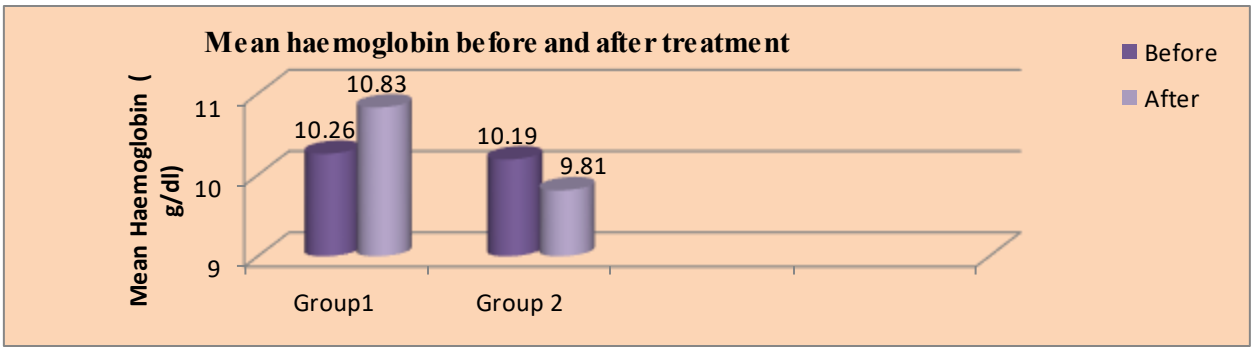
Of the 48 participants, 42 (87.5%) were female and six (12.5%) were male. In Group 1, which received Lecithinum 12C with Ferrum phosphoricum 6X, mean haemoglobin increased from 10.26 to 10.84 g/dl, and 23 of the 24 participants (95.8%) showed improvement. In Group 2, which received Lecithinum 12C with placebo, mean haemoglobin decreased from 10.20 to 9.81 g/dl, and no participant showed an increase. These results indicate a difference in the observed changes between the two groups, as summarised in Table 1 and illustrated in Figure 1.The reported between-group t-value of 2.671 was interpreted by the study authors as exceeding the critical value at the 5% significance level. On this basis, the null hypothesis was rejected and the alternative hypothesis was accepted.

Table 1. Change in haemoglobin (g/dl) after treatment

Group	n	Mean before	Mean after	Mean change ± SD	t (df 23)	p
Group 1 (Lec 12C + Ferr phos 6X)	24	10.26	10.84	+0.575 ± 0.265	10.59	< 0.0001
Group 2 (Lec 12C)	24	10.20	9.81	−0.383 ± 0.231	−8.10	< 0.0001
Between groups				Difference 0.958	2.671 (df 46)	< 0.0001

Figure 1. Graph showing mean haemoglobin before and after treatment in lecithinum 12C and with ferrum phos 6X group and lecithinum 12C.

Fatigue followed a similar pattern, as shown in Figure 2. The mean FACIT-F score improved by 5.38 ± 5.57 points in Group 1 and declined by 4.50 ± 4.90 points in Group 2. The report gives a between-group difference of 9.88 points and states that the difference was statistically significant. FACIT-F scores improved in 21 of 24 participants (87.5%) in Group 1 and in two of 24 participants (8.3%) in Group 2.



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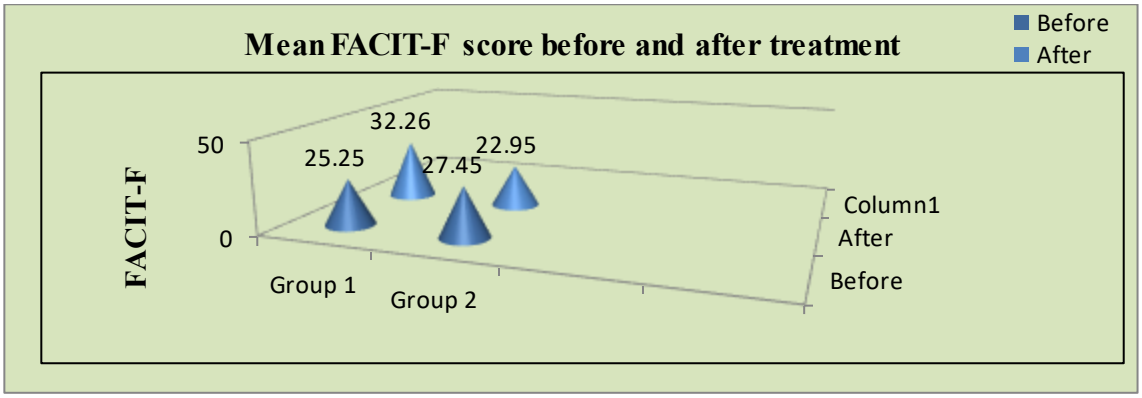

When haemoglobin response was examined by age group (Figures 3 and 4), improvement in Group 1 was observed in 14 of 14 participants aged 10 to 20 years, four of four aged 21 to 30 years, three of four aged 31 to 40 years and two of two aged 51 to 60 years. No participant in Group 2 showed haemoglobin improvement in any of the reported age groups.

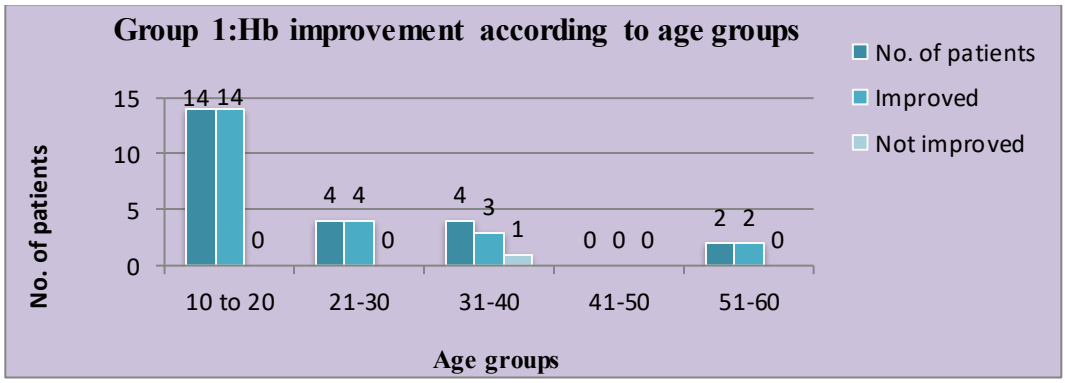

Figure 3. Graph showing Hb improvement according to age groups in lecithinum 12C and ferrum phos 6X group .

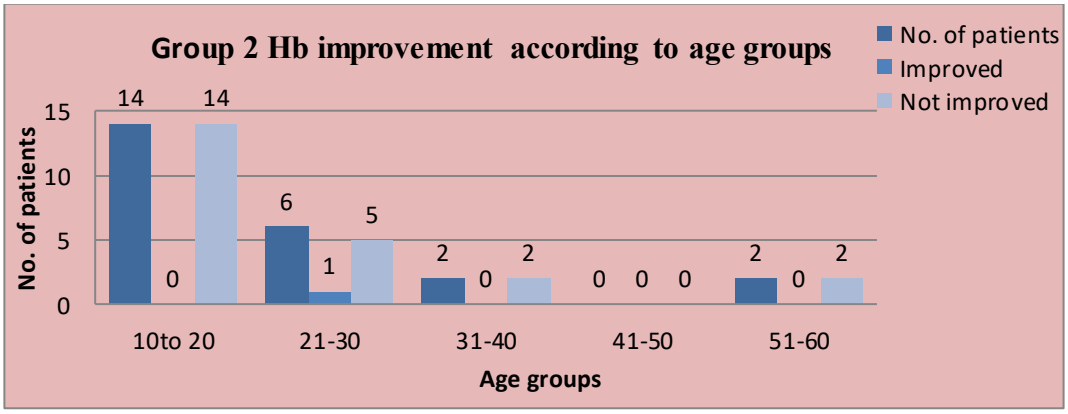

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Fig 4 : Graphical representation of Hb improvement according to age groups in group of lecithinum 12C.

By sex (Figures 5 and 6), haemoglobin improved in three of three males and 20 of 21 females in Group 1, whereas no improvement was reported among either males or females in Group 2. The small numbers in some subgroups limit reliable comparisons by age and sex.

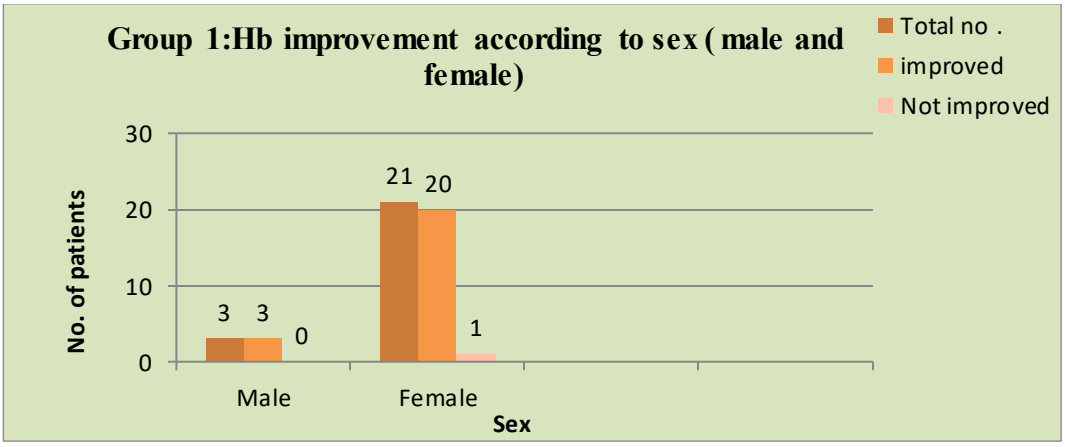

Figure 5. Graphical representation of improvement in Hb according to sex (male a nd feamale) in combination group of lecithinum12C and Ferrum phos 6X

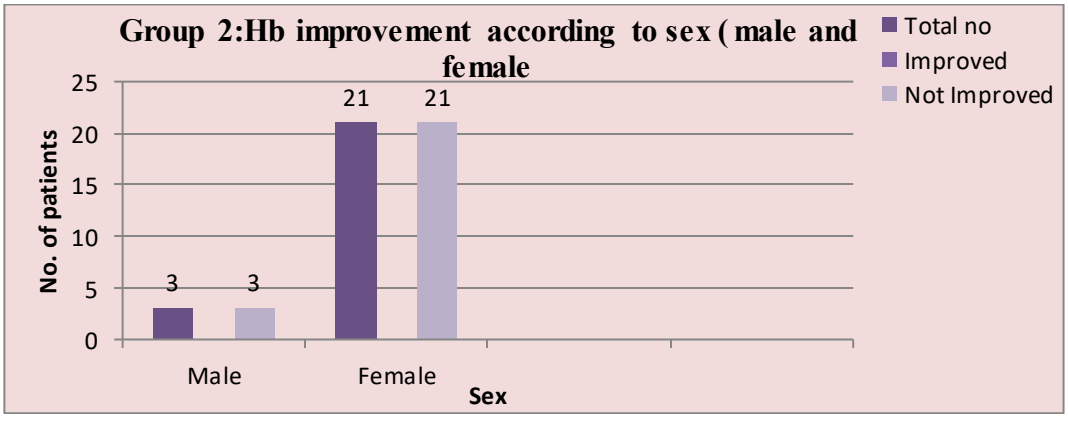

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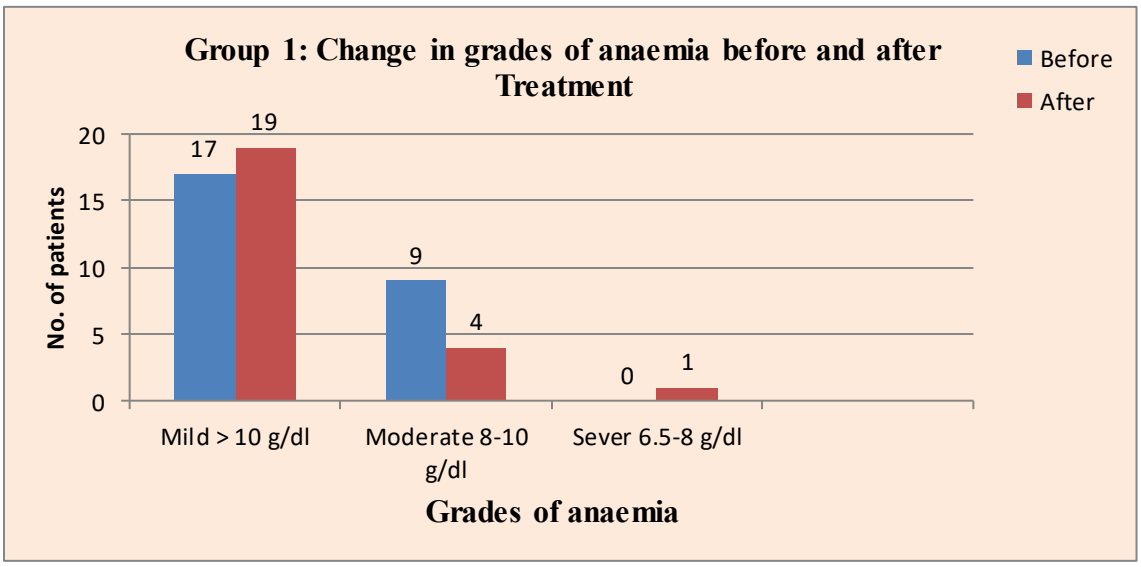
Figure 6. Graphical representation of improvement in Hb according to sex (male a nd feamale) in combination group of lecithinum12C

The grades of anaemia before and after treatment are shown in Table 3 and in Figures 7 and 8. In Group 1, the number of participants with mild anaemia increased from 17 to 19, while the number with moderate anaemia decreased from seven to four, and one participant was classified as having severe anaemia after treatment. In Group 2, mild anaemia decreased from 15 to 12 participants, and moderate anaemia increased from nine to 12. These changes in category should be interpreted alongside the individual haemoglobin results.

Table 3. Grades of anaemia before and after treatment

Grade	Group 1 before	Group 1 after	Group 2 before	Group 2 after
Mild	17	19	15	12
Moderate	7	4	9	12
Severe	0	1	0	0

Fig 7:Graphical representation of Grades of anaemia of Lecithinum 12C and Ferrum phos 6X group.



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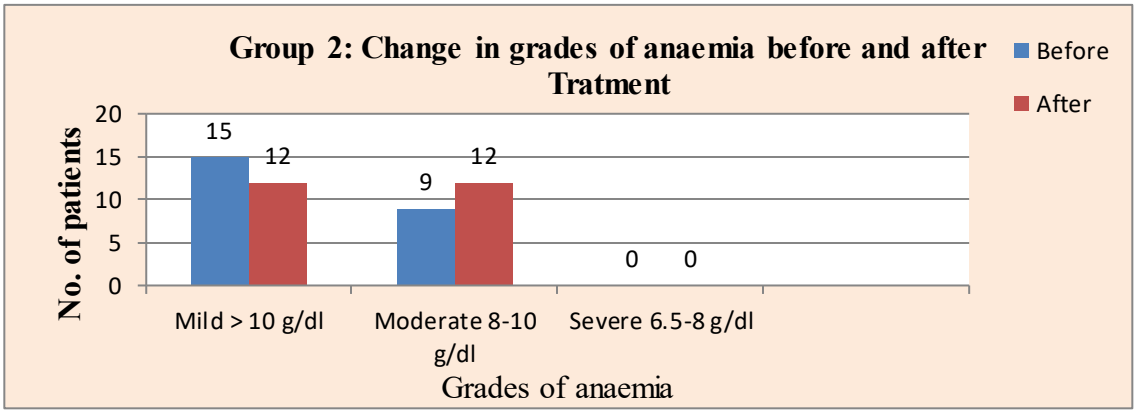

Figure 8.Graphical representation of Grades of anaemia of Lecithinum 12C

Discussion

Females accounted for 87.5% of the participants, and the 10 to 20-year age group was the largest. This pattern is consistent with national reports of a high burden of anaemia among adolescent girls and women of reproductive age (11, 12). Menstrual blood loss, increased iron requirements during growth and inadequate dietary iron intake are potential contributing factors.

Participants who received Lecithinum 12C with Ferrum phosphoricum 6X showed an average haemoglobin increase of approximately 0.58 g/dl, and 95.8% of them improved. In contrast, the group receiving Lecithinum 12C with placebo showed an average decrease of approximately 0.38 g/dl, and none of its participants improved, so that the between-group difference was approximately 0.96 g/dl. Although this finding is consistent with the earlier reports discussed by the authors (4–8), the absolute increase was modest, and the study was not designed to establish that haemoglobin was restored to normal. Because there was no untreated or placebo-only arm, the reason for the decline in the control group cannot be determined, and the study cannot establish the combination as a replacement for standard anaemia management.

Fatigue scores improved in the combination group and worsened in the control group. The use of the FACIT-F scale adds a patient-reported outcome to the laboratory measurement. The authors noted that ongoing blood loss, irregular intake of medicine, associated nutritional deficiencies, a diet low in iron and heavy physical work may have limited symptom improvement in some participants.

Haemoglobin improvement was observed across the reported age groups and in both sexes in Group 1. However, only three males were enrolled in each group, and no participants were represented in the 41 to 50-year category in the subgroup results. The study therefore provides limited evidence for reliable conclusions about differences between age groups or sexes.

The distribution of anaemia grades shifted towards a greater number of participants with mild anaemia in Group 1, whereas moderate anaemia became more common in Group 2. One participant in Group 1 was classified as having severe anaemia after treatment, which underscores the need for individual clinical monitoring rather than reliance on group averages alone.

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Study limitations

The study had a small sample drawn from a single centre, which limits the generalisability of the findings and the statistical power of the subgroup analyses. The follow-up period did not establish whether any benefit was sustained. There was no conventional iron-treatment comparator and no separate placebo-only group, and dietary intake, treatment adherence and coexisting deficiencies were not controlled.

Further research should therefore include larger, multicentre randomized trials with longer follow-up and a conventional iron-treatment comparator. Such studies would help to verify the present findings and to examine whether responses differ by age or sex.

Conclusion

In this study, the group receiving Lecithinum 12C combined with Ferrum phosphoricum 6X showed a greater observed improvement in haemoglobin and in fatigue scores than the group receiving Lecithinum 12C with placebo. Haemoglobin improved in 95.8% of participants in the combination group, whereas no increase was reported in the control group. These findings are preliminary because of the small sample and the methodological limitations. The combination should not be regarded as a substitute for conventional diagnosis, for iron replacement when indicated, or for other evidence-based treatment of anaemia.

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External Sorce

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